SEP 30 2005

K 050097

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510(k) SUMMARY

510(k) Owner's name:	TechTrade
Address:	274 Madison Ave. S-1001 New York, NY 10016
Phone:	212-481-2515
Fax number:	212-481-2487
Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 Fax: 949-552-2821

Date the summary was prepared: September 26, 2005

Name of the device:	Techno-Scope™ Visual Stethoscope
Trade or proprietary name:	Techno-Scope™ Visual Stethoscope
Common or usual name:	Stethoscope
Classification name:	Electronic Stethoscope (21 CFR 870.1875, Product Code DQD)

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Applicant	Device	510(k)
CADITEC AG	CADISCOPE ELECTRONIC STETHOSCOPE	K990809

Description of the device:

The Techno-Scope™ Visual Stethoscope is comprised of a manual stethoscope which can project sounds associated with the heart, arteries, veins and other internal organs. It also has

an electrocardiograph (ECG) display unit. The electrocardiograph consists of 3 leadless nondisposable electrodes. It is placed on the chestpiece of the stethoscope, opposite the diaphragm. It can display real time ECG through high resolution LCD. It also calculates and displays the heart rate according to the ECG. The healthcare professional can listen to internal organ sounds simultaneously while seeing the ECG signals.

Indications for Use:

The Techno-Scope projects sounds associated with the heart, arteries, and veins and other internal organs. It also acquires the electrical signal from electrodes and produces a visual display of the electrocardiograph signal and heart rate.

The Techno-Scope is not intended to be used as a diagnostic device.

Summary of the technological characteristics of the Techno-Scope

The predicate was compared in the following areas and, with the except that the predicate device is an electronic stethoscope and the Techno-Scope is a manual stethoscope, found to have similar technological characteristics and to be equivalent to the CADIscope.

Biocompatibility
Display of cardiac biopotentials
Environment
Indications
Intended Use
LCD Display
On/Off Controls
Patient Contacting Materials
Power Supply
Signal Storage
Sound Amplification
Sound Pickup
Target Population

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2005

TechTrade LLC
c/o Ms. Grace Holland
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, California 92606

Re: K050097
Trade Name: Techno-Scope™ Visual Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: August 31, 2005
Received: August 31, 2005

Dear Ms. Holland:

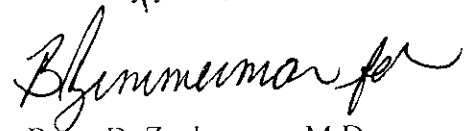
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K050097

Device Name: Techno-Scope

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The Techno-Scope is not intended to be used as a diagnostic device.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050097